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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,796	04/18/2005	Michael P Doyle	31725-77556	2317
23643	7590	07/11/2007	EXAMINER	
BARNES & THORNBURG LLP 11 SOUTH MERIDIAN INDIANAPOLIS, IN 46204			AFREMOVA, VERA	
		ART UNIT	PAPER NUMBER	
		1657		
		MAIL DATE	DELIVERY MODE	
		07/11/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,796	DOYLE ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 June 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 10-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 10-19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/18/2005</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the Group II (original claims 10-13) in the reply filed on 6/11/2007 is acknowledged. Non-elected claims 1-10 were canceled by applicants.

Claims 10-13 as amended and new claims 14-19 (6/11/2007) are under examination in the instant office action.

Claim Rejections - 35 USC § 112

Indefinite

Claims 11-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 11, 12, 14 and 19 the sole designation of bacterial strains by the internal designation numbers 31-6, 47-10, 50-10, 58-9, 59-9 small, 59-9 big, 71-8 and 76-9 creates ambiguity in the claims. For example, the strains disclosed in this application could be designated by some other arbitrary means, or the assignment of the strain names could be arbitrary changed to designate other strains. If either event occurs, one's ability to determine the metes and bounds of the claims would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204,208 (CCPA 1070). Amendment of the claims to refer to the deposit accession number of the claimed strains in culture collection with IDA status would obviate this rejection.

Deposit

Claims 11-19 are rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to specific microorganisms numbers such as bacterial isolates 31-6, 47-10, 50-10, 58-9, 59-9 small, 59-9 big, 71-8 and 76-9. Because the microorganisms are essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganisms are not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by deposit of the microorganisms. The specification does not disclose a repeatable process to obtain the microorganisms and it is not clear from the specification or record that the microorganisms are readily available to the public.

The rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37 CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

Because ATCC has acquired the status of an International Depository in accordance to the Budapest Treaty, a declaration stating that all restrictions will be irrevocably removed upon

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issuance of the patent will overcome this rejection. Please, provide also copies of deposit receipts for the record.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-19 are rejected under 35 U.S.C. 102(b) as anticipated by US 5,478,557 (Nisbet et al) or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 5,478,557 (Nisbet et al).

Claims are directed to a composition comprising probiotic bacteria capable to inhibit *Salmonella*. Some claims are/are further drawn to incorporation of a carrier and/or animal feed into the composition. Some claims are further drawn the forms of composition such as liquid or paste. Some claims are further drawn to incorporation of carrier materials that promote viability of the probiotic bacteria. Some claims are/are further drawn to the isolates 31-6, 47-10, 50-10, 58-9, 59-9 small, 59-9 big, 71-8 and 76-9.

US 5,478,557 (Nisbet et al) discloses a composition comprising probiotic bacteria effective for controlling *Salmonella* colonization of animals (entire document including abstract,

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col. 3, lines 34-68). The cited patent discloses various forms of composition including stock cultures, paste, protective encapsulation, liquids, etc. (from col. 7, line 12 to col. 8, line 30).

The referenced probiotic bacteria appear to be identical to the presently claimed bacteria and/or isolates and they are considered to anticipate the claimed microorganisms since these bacteria are probiotic bacteria effective in controlling Salmonella in animals. Consequently, the claimed isolates and compositions therewith appear to be anticipated by the reference.

In the alternative, even if the claimed microorganisms are not identical to the referenced strains with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganisms are likely inherently possess the same characteristics of the claimed microorganisms particularly in view of the similar characteristics which they have been shown to share such as capability of inhibiting Salmonella. Thus, the claimed isolates and compositions therewith strain would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Therefore, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

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The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

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July 7, 2007



VERA AFREMOVA

PRIMARY EXAMINER